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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,276	12/06/2001	Roy L. Barrus	S-8492 (1502-71 CIP II)	4052
55825	7590	06/21/2007	EXAMINER	
CARTER, DELUCA, FARRELL & SCHMIDT, LLP			WILLIAMS, CATHERINE SERKE	
445 BROAD HOLLOW ROAD			ART UNIT	PAPER NUMBER
SUITE 225			3763	
MELVILLE, NY 11704			MAIL DATE	DELIVERY MODE
			06/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/016,276	BARRUS ET AL.
	<b>Examiner</b> Catherine S. Williams	<b>Art Unit</b> 3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 09 April 2007.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-5,7,8,11-14,33 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 33 and 35-37 is/are allowed.
- 6) Claim(s) 1-5,7,8,11-14 and 38-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                        |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____.  |

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3,5,7,38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (USPN 6,824,530) in view of (USPN 4,735,618 ('618); 4,898,589 ('589); 5,250,031 ('031); or 5,256,152 ('152)).

Wagner discloses a device including a ninety degree angle needle (16) having a distal portion and a proximal portion. See figures 3 and 14-17. The device also includes a shield (see figure 17) having at least one elongated part (46), a proximal end mounted with the proximal end of the needle, a distal end mounted with a planar contact surface (56) and a hub with appendages (44). See also figures 14-17. The shield is extensible between a retracted position (figure 14) and an extended position (figure 17) via fixed positioning of the planar contact surface relative to movement of the shield. Regarding the claim limitation of "via fixed positioning of the planar contact surface relative to movement of the shield", see the disclosure of the operation of the needle 4:60-5:16. The device also includes a distal end of the foldable legs (46) of the shield being hingedly attached to the circular portion (56) of the planar contact shield (56) via linear bearing (54). The needle and the shield segments are moveable in relation to the linear bearing. See figures 14-17.

Wagner meets the claim limitations as described above but fails to include the needle linear bearing defining a throughbore having a diameter that is substantially equal to an external diameter of the needle. However, each of the references above ('618); ('589); ('031); or ('152) teach a linear bearing that has a throughbore having a diameter that is substantially equal to an external diameter of the needle

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 102(e) as being anticipated by Wagner in view of ('618); ('589); ('031); or ('152) in further view of FR2803529. Wagner in view of ('618); ('589); ('031); or ('152) meets the claim limitations as described above but fails to teach the appendage having at least one opening. However, FR2803529 discloses such an appendage with at least one opening.

At the time of the invention, it would have been obvious to incorporate the at least one opening as taught by FR2803529 into the invention of Wagner in view of ('618); ('589); ('031); or ('152). The motivation for the incorporation would have been commonly known by one skilled in the art. The motivation would have been to provide an attachment point for tape or another attachment mechanism to enhance the adhesion of the device to the patient during use.

Claims 8 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner in view of ('618); ('589); ('031); or ('152) in further view of Bell (US Pat# 5,997,504). Wagner in view of ('618); ('589); ('031); or ('152) meets the claim limitations as described above but fails to teach the planar contact surface having a pad, an anchor part, and texturing.

Bell discloses a safety shield apparatus including needle (16,18) and a shield (see figures 12A-12C). The shield includes at least one elongated part with a proximal end mounted with the proximal portion of the needle and a distal end mounted with a planar contact surface (120). The planar contact surface also has a linear bearing (131) that slidably facilitates movement of the needle relative to the shield. See figure 11. The shield is shown being extensible between a retracted position and an extended position via relative movement between the surface (120) and the proximal portion of the shield (see figures 12A-12C). The device further includes a needle hub (104), an appendage wing (44), segment (28) and channel (inside 28). A latch (112) is shown in figure 12D with an arm having a plurality of surfaces including an arcuate surface. The needle is angularly displaced approximately 90 degrees (see figure 4A). **The planar contact surface includes an anchor/pad (122) which is an adhesive pad (texturing due to the adhesive).** The distal end of the shield is hingedly attached to the contact surface (see figures 12A and 12B).

At the time of the invention, it would have been obvious to incorporate the teaching of the pad/anchor of Bell on to the planar contact surface of Wagner in view of ('618); ('589); ('031); or ('152). The devices are analogous in the art of needle shields and therefore a combination is proper. Additionally, the anchor/pad of Bell facilitates an efficient and comfortable securing of the device to the patient. See paragraph 37 of Bell. Additionally, one

skilled in the art would recognize the advantage of having a comfortable and secure attachment mechanism to the patient. The disclosure of Wagner states that in the operation of the device one has to hold down the planar contact surface while pulling up the needle hub. See step 3 at 5:1-9. One skilled in the art would recognize that having an adhesive pad/anchor on the device of Wagner would eliminate the need for holding down the planar contact surface; thus, making the device of Wagner easier to use.

Claims 11-13 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (USPN 6,824,530) in view of ('618); ('589); ('031); or ('152) in further view of Kuracina et al (US Pat# 5,879,337).

Wagner in view of ('618); ('589); ('031); or ('152) meets the claim limitations as described above but fails to include the linear bearing that slidably engages the needle having a latch. However, Kuracina discloses such a linear bearing having latch. The device includes a latch (41) engageable with the needle where the latch includes an arm (see figures 30-31) for maintaining the shield in the extended position (see figure 31) and a plurality of surfaces (the distal end and side surface of the interior of the latch arm (41) configured to maintain the shield in the extended position (see figure 31).

At the time of the invention, it would have been obvious by one skilled in the art to modify the distal end interior of the needle shield (54) of Wagner (the embodiment of figure 14-17) in view of ('618); ('589); ('031); or ('152) by incorporating the latch (41) as taught by Kuracina (figures 30-31). Both devices are analogous in the art of needle shields; therefore, a combination is proper. Additionally, as taught by Kuracina, the latch (41) works to

automatically entrap or capture the sharpened tip of the needle after use (see 3:26-28). One skilled in the art would recognize the advantage of having a needle mechanism that “automatically” entraps the tip of the needle when the shield is actuated. Wagner fails to provide this type of entrapment and the motivation for the incorporation would have been to enhance the shielding of the needle by the Wagner shield with an entrapment mechanism. This incorporation would also enhance the safety to the medical technician during the use of the device.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner in view of ('618); ('589); ('031); or ('152) in further view of Kuracina. Wagner in view of ('618); ('589); ('031); or ('152) in further view of Kuracina meets the claim limitations as described above but fails to include the latch having an arcuate surface being engageable with the needle.

However, it would have been an obvious matter of design choice by one skilled in the art to make the inside surface of the needle latch either at a right angle as shown in figures 30-31 of Kuracina or having a curved corner as claimed. Applicant has not discloses that the latch having an arcuate surface solves a particular problem, is used for a particular purpose or provides an advantage. Furthermore, one would expect Kuracina's latch and applicant's arcuate surface latch to perform equally well given that both would perform the function of retaining the needle within the shield given that, in the prior art, it is the inside distal surface of the latch that prevents the needle tip from being accessed after use. The prior art latch performance would not be affected with either a curved latch or a latch having a right angle. Therefore, the modification would have been considered a mere obvious design choice that fails to patentably distinguish over the prior art.

***Allowable Subject Matter***

Claims 33,35,36 and 37 are allowed.

***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3763

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Catherine S. Williams/*  
Catherine S. Williams  
Primary Examiner, Art Unit 3763  
June 18, 2007